Review of materials submitted to EPA for Seal Shield Electroclave

Materials for review were emailed to EPA's Antimicrobials Division (POC- K. Willis) from Mr. Christian Davis of SealShield on 5/1/2020. The materials were reviewed by Sophie Nguyen and Kristen Willis from the Antimicrobials Division.

EPA had a follow up call with Seal Shield on 6/9/2020 to go over the review and outstanding questions. Seal Shield provided responses to the outstanding questions that EPA had by email on 6/10/2020 which are noted in red below.

Documents provided:

- Peer reviewed article, Boyce et al. "Impact of Room Location on UV-C Irradiance and UV-C Dosage and Antimicrobial Effect Delivered by a Mobile UV-C Light Device". 2016. Infection Control & Hospital Epidemiology
- UV-C Dosimetry Testing Summary prepared by SealShield
- Electroclave In Vitro Study- Microchem Labs- MRSA and CRE
- Electroclave In Vitro Study- Microchem Labs- *S. aureus* and *E. coli*
- EPA LED In Vitro Study Dosages
- ILT2400 Radiometer Data Sheet
- IUVA_UVC Dosage Chart
- Manufacturing QC on UVC LEDs
- Peer reviewed article, Dai et al, "Ultraviolet C Irradiation: An Alternative Antimicrobial Approach to Localized Infections" 2012. Expert Rev. Anti. Infect Ther.
- UVC LED Specs
- UVC LEDs vs Mercury
- Electroclave user manual
- SSURA amendment draft 6-10-2020

Summary of Materials:
Apparatus is a container device with UV-C LED bulb.

UV-C Dosimetry Testing Summary: In vitro studies were done using modified ASTM E1153 to measure the dosage using 5 ElectroClaves. The minimum dosage measured was 89.25 mJ/cm2 in Disinfection Bay #3. This value was compared to peer-reviewed articles where testing was conducted against *E. coli*, *S. aureus*, MRSA, VRE, and *C. difficile* using dosages lower than 89.25 mJ/cm2. Log reductions observed in the peer reviewed publication were 5 $\log_{10}$ for *E. coli*, *S. aureus*, and VRE, 4 $\log_{10}$ for MRSA, and 1-3 log for *C. difficile*. Some of these studies are not applicable to environmental surfaces or to certain testing conditions captured in lab studies specific to ElectroClaves. Peer review limitations were reported.

Disinfection Bay #3 demonstrated the lowest dosage across all 5 ElectroClaves.

ElectroClave SN#	Disinfection Bay	Measured Dosage (mJ/cm^2)

080300006	1	134.60
080300006	2	90.65
080300006	3	89.25*
080300006	4	98.62
061800014	1	134.2
061800014	2	90.60
061800014	3	90.05
061800014	4	98.58
080300032	1	134.45
080300032	2	90.60
080300032	3	89.55
080300032	4	98.60
080300001	1	134.55
080300001	2	90.58
080300001	3	90.15
080300001	4	98.61
080300012	1	134.35
080300012	2	90.52
080300012	3	90.10
080300012	4	98.58

In vitro studies: In Vitro studies were done using Seal Shield's Electroclave at Microchem Lab using ASTM E1153 (sanitizer for use on non-food contact surface). Glass slide carriers were inoculated only on the upward facing surface.

Log reductions after three contact times:

Organisms	**6 m 16 s**	**13 m 33 s**	**20 m**
S. aureus	~5.52 log reduction (glass slide)	-	6.37 log (cell phone)
E. coli	~5-6 log (glass slide)	-	2-3 log (cell phone)
MRSA (glass slide)	2.99 log	3.69 log	4.65 log
CRE (glass slide)	3.53 log	3.64 log	4.10 log

Remaining Questions:

1. For cell phones as carriers, which area of the phone was inoculated and how was it recovered?

Response: The glass screen was spot inoculated to create a ~1 square inch area. At the conclusion of the test, samples being irradiated in the ElectroClave were removed and the carriers were chemically neutralized.

2. Can the results be extrapolated to every surface area or only the inoculated area close to the dosage measured/LED light?

Response: Our lighting design has each of the LEDs lighting cones intersecting each other at their full width half maximum (FWHM). This is determined by knowing the proper specifications of your LED and performing the calculations of the viewing angle. The LED irradiance profile can then be simulated. We have verified the uniformity of the LED irradiance profile using a radiometer. We

have two different radiometers which we utilize to quickly and easily empirically confirm the performance of our product and to evaluate the performance of third party products.

3. Where are the LED bulbs within the Electroclave chamber? How many bulbs are there?

Response: The UV-C LEDs are below and above each disinfection bay. There are 17 LEDs in total for each disinfection bay, with a total of 68 LEDs in the entire cabinet.

4. Is the dosage emitted at every Disinfection Bay measured throughout the tray or at the area closest to the UV-C LED source? These questions also apply to the glass slides. It looks like only the exposed surface gets a direct hit.

Response: Yes, the dosage is measured throughout the tray and we highlighted the low dosage values in the dosimetry report. Surfaces get direct hits from the entire viewing angle of each LED as our design has the lighting cones intersecting at FWHM.

5. What effect will items placed on the trays have on efficacy? For example, if each tray had 3 cell phones, would the cell phones impede the UV-C light from reaching the phones on other trays depending on where the light source is?

Response: No, each tray is independently irradiated. Therefore, items placed on one tray will not impact the irradiation of items on other trays.

6. How does the soil load used in these in vitro studies, if any, account for the actual bio burden found on the objects treated in real-life settings? Little information is provided concerning the soil load utilized in these two studies. Boyce et al. recognized the effect that "different levels of organic material might have had on log reductions of pathogens achieved" (p. 5).

Response: Soil loading was not used in the studies. We withheld soil loading as it was not required to determine efficacy of our UV-C dosages. Furthermore, we do not claim a 1 step cleaner/sanitizer, as we instruct the users to clean each non-porous and hard surface device prior to a disinfection.

Additional questions raised on the call on 6/9/2020 with responses provided by Seal Shield in red:

1) Specific information concerning where Seal Shield plans to place the EPA Producer Establishment number on its packaging and labeling for the device.

Response: In the Box.net linked folder ([HYPERLINK "https://gcc01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsealshield.box.com%2Fs%2F1s85pdbr6n14v7qyh5g27hvr58r029vq&data=02%7C01%7CWillis.Kristen%40epa.gov%7C57158047de4640e0295008d80d7bc502%7C88b378b367484867acf976aacbeca6a7%7C0%7C0%7C637274172540058858&sdata=hTON1D7hGAWA6orpOEUUffhjUpbKTkT%2BfXtEbQlt0ZQ%3D&reserved=0" \t "_blank"]), I have placed the artwork for the carton packaging in which every ElectroClave ships. It contains the EPA Producer Establishment number.

2) The specific claims that Seal Shield is proposing to use for the marketing, packaging and labeling of the ElectroClave device. The proposed claims should follow the parameters discussed during yesterday's call, i.e., the claims that are substantiated by Seal Shield's submitted data for the three (3) tested pathogens (E.coli, MRSA and S. aureus) that support the device's effectiveness on hard non-porous surfaces

Response: I believe Kristen Willis indicated that the data we supplied concerning four tested pathogens substantiated efficacy for those four tested pathogens (MRSA, E.coli, S. aureus and CRE). If that isn't correct, please let me know, as we tailored the below claim to what we thought she'd said on yesterday's call. At this time, Seal Shield proposes to make the following claim: The

ElectroClave can achieve a 99.9% reduction of MRSA, E.coli, S. aureus and CRE on hard, non-porous surfaces. NOTE: EPA-OPP verified that this is accurate.

Additional information from the call on 6/9/2020

1) The Electroclave maintains a positive pressure in addition to filtration of air coming into the cabinet. This reduces dust and another soil in the cabinet itself.
2) The Electoclave utilizes a proprietary quartz material in the bays which transmits 99.9% of the UVC so there are no shadows. This is different from other technologies which utilize reflection off of a mirrored surface.
3) A user manual is provided to each user. There is a specific section for cleaning and disinfecting:

   "The ElectroClave's UVC LED light will not penetrate organic or inorganic matter. Regular cleaning of devices prior to disinfection in the ElectroClave is strongly recommended. Cleaning should involve a wiping process where organic and inorganic material is removed from the surface of the device. Please consult with your local infection control practitioner for protocols on wiping device surfaces and establishing disinfection frequency."
4) The manual also specifies that the Electroclave is only for non-critical medical devices.

Conclusions- Revised 6-15-2020:

Seal Shield has conducted efficacy data as well as provided dosage information across 5 devices and references to peer review studies in relation to their own device. Note that some of the peer review articles referenced are not applicable to surfaces (e.g., water) or to certain testing conditions used in lab studies for ElectroClaves. Additionally, peer review limitations were reported (e.g., "our findings cannot be considered representative of all such devices" (Boyce et al., 2016, p.671)). The dosage information provided across the 5 devices resolves our concerns about reproducibility.

Since EPA does not have testing standards for devices, we cannot determine if the data submitted achieve an acceptable level of efficacy against the organisms tested. However, the studies conducted using Seal Shield's device are applicable to the specific conditions utilized (e.g., contact times, irradiance level, exposed areas, type of carriers used, soil load used, performance observed, organisms tested). Therefore, our recommendation is that claims and advertisement statements should be limited to reflect results from the studies conducted using their own device to ensure the most accurate use directions and conditions are followed.

Specific claims in the amended SSURO dated 6-10-2020 (paragraph 5):

1) "No disease prevention claims shall be made regarding the effectiveness of the ElectroClave device;
2) Efficacy (log reduction) claims shall be limited to 99.9% reduction and only as to those pathogens for which data has been generated, which, to date, include Staphylococcus, Escherichia coli, Methicillin-Resistant Staphylococcus Aureus and Carbapenem-Resistant Enterobacteriaceae; and

3) Distribution shall be accompanied by a User Manual that identifies the need for mechanical removal of bio-burden and the importance of hand hygiene"

OPP agrees that the specific efficacy claim above is supported by the data and concurs that no disease prevention claims should be made and that the manual should identify need for mechanical removal of bio-burden and the importance of hand hygiene. It would be helpful if Seal Shield could identify some ordinary examples of "organic and inorganic" material in the manual to provide clarity to the user. Please note that efficacy claims shall be limited to 99.9% reduction on hard, nonporous surfaces for the pathogens for which data had been generated.